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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,323	05/05/2005	Donatienne Denni-Dischert	PC/4-32676A	6762

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
CHUNG, SUSANNAH LEE	
ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
07/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,323	DENNI-DISCHERT ET AL.	
	Examiner	Art Unit	
	SUSANNAH CHUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-6, 8-11, and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-6, 8-11 and 13-15 are pending in the instant application. Claims 4, 7, and 12 are canceled. Claims 14 and 15 are new.

Response to Non-Final Office Action

Acknowledgment is made of applicant's response and amendment of the claims filed on 5/1/2008.

Claim 8 was rejected under 35 U.S.C. 102(b) as being anticipated by Buhlmayer, et al (U.S. Pat. No. 5,399,578 (`578 Patent)). Applicants amendments to the claims have been considered, but are not found persuasive. The moieties R1 and R2 still read on the prior art. R1 is a tetrazole protecting that is C1-C2-alkyl that is monosubstituted by phenyl, wherein the phenyl ring is unsubstituted and R2 is a carboxy protecting group that is C1-C2-alkyl that is monosubstituted by phenyl, wherein the phenyl ring is unsubstituted. Therefore, as stated in the previous office action, the compound of claim 8 is anticipated by the prior art and this rejection is maintained.

Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over Buhlmayer, et al (U.S. Pat. No. 5,399,578 (`578 Patent)). Applicants arguments have been considered, but are not found persuasive. As stated in the previous office action, it is asserted that converting an amine (wherein the amine contains single bonds) to an imine (wherein the amine functional group contains a carbon-nitrogen double bond) is obvious to one of ordinary skill in the art. Imine formation is well known in the art as amines react with ketones and aldehydes to form imines. Therefore, this rejection is maintained.

Claims 1-7 and 10-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Markwalder et al., U.S. Pat. Num. 5,260,325 (`325 Patent). Applicants arguments have been considered, but are not found persuasive. Applicants argue that the addition of water to the reaction is novel and unobvious. Applicants also argue that the prior art does not teach the addition of water. Examiner respectfully disagrees. The addition of water to the reaction is taught by the prior art. See `325 Patent, Example 1, part C, column 14, approximately lines 34-36, wherein the amide was treated with a mixture of acid and water and there is also water in the workup. In addition, Example 2, part D, column 15, approximately lines 62-64, wherein water was added to the reaction mixture and then used again prior to the workup. The instantly claimed compounds are water soluble and the use of water is taught by the prior art. Therefore, the instantly claimed process claims are obvious in view of the prior art.

Claim Rejections - 35 USC § 103

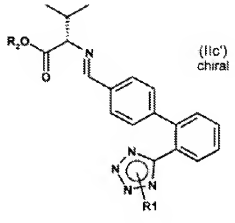
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

New Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buhlmayer, et al (U.S. Pat. No. 5,399,578 (`578 Patent)).

Applicant claims a compound of formula, 

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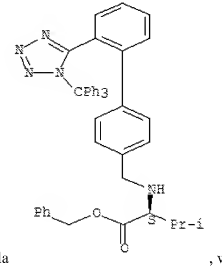
Determination of the scope and content of the prior art (MPEP § 2141.01)

Buhlmayer teaches a compound of formula 

, which corresponds to Applicants instant claim 9, wherein R1 is a tetrazole protecting group, i.e. triphenylmethyl, and R2 is a carboxy protecting group. (See `578 Patent, Column 50, approximately lines 46-48, Example 55(a), N-[(2'-(1-Triphenylmethyltetrazol-5-yl)biphenyl-4-ylmethyl]-(L)-valine benzyl ester, CAS RN 137864-45-0).

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Buhlmayer and the instant claims is that the prior art compound has a single bond (amine), while the instant claim has a C=N double bond (imine) and that the prior art compound is racemic or S, but does not explicitly disclose the R form.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Buhlmayer to make products useful as angiotensin receptor blockers, wherein a single bond (amine) is converted to a double bond (imine). It is asserted that converting an amine (wherein the amine contains single bonds) to an imine (wherein the amine functional group contains a carbon-nitrogen double bond) is obvious to one of ordinary skill in the art. Imine formation is well known in the art as amines react with ketones and aldehydes to form imines.

In addition, the stereochemistry of the instantly claimed compound may not be the preferred enantiomer, but Buhlmayer does disclose the racemic compound and the S-enantiomer. A stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. In re Anthony, 162 USPQ 594, 596 (1969) and In re Adamson, 125 USPQ 233, 234 (1960).

Guided by the teaching of Buhlmayer one skilled in the art would be able to make similar compounds. The motivation would be to prepare similar compounds that are pharmacologically active compounds that are angiotensin receptor blockers.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626

Susannah Chung, July 2, 2008